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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,190	08/09/2001	Hillel Glover	G5072.0001/P001	4263

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,190

Applicant(s)

GLOVER, HILLEL

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

Claims 1-23 are pending in this application.

Response to Arguments

Applicant's arguments filed 20 May 2003 have been fully considered but they are not persuasive. The rejection made in paper number 7 over Dante ('091) and Carlezon Jr. ('075) under 35 U.S.C. §103(a) is maintained and is hereby repeated.

Applicant asserts that dissociation-related conditions are nowhere to be found in Dante. Applicant also asserts that Dante fails to suggest a dissociation-reversing amount of an opiate antagonist and instead provides a general dosage range.

Dante teaches use of opiate antagonists along with typical anti-depressants for the treatment of refractory depression (columns 2-3) as well as depression with anxiety. The dose of Trexan is 10-150mg per day, given along with other antidepressants such as tricyclics. Carlezon Jr. teaches the use of Kappa receptor antagonists for treatment of major depression and *post traumatic stress disorder*, from with the dissociative symptoms appear (as recited in the DSM-IV under Acute Stress Disorder). Regarding the assertion that the Dante patent fails to recite "in need thereof", claims not specifying the subset of patients to be treated in this manner are generally viewed as meeting the claims of any prior art method using the given agent since they read on administration to the general population and not only the specified subset requiring treatment.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glover U.S. Patent No. 5,028,612.

The claims are drawn to a method for treating refractory depression characterized by dissociation, comprising administering to a patient an effective opiate antagonist such as, nalmefene or salt thereof and an antidepressant, the opiate antagonist having pentacyclic nucleus for oral administration and method of evaluating response to the opiate antagonist.

Glover teaches an opiate antagonist or pharmaceutically acceptable salt thereof for treatment of emotional numbness.

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It does not specifically recite dissociation, however, the symptoms instantly recited, and labeled as dissociation in the instant case are all disclosed in the Glover patent (see columns 1-2). The case study (column 8, Example 2) is drawn to the effectiveness of the narcotic antagonist for the symptoms of dissociation, however, column 9, lines 20-25 recite a case history of Mrs. Smith, who became depressed while on the naltrexone for symptoms of dissociation. A tricyclic antidepressant was added with a very positive response.

Dependent claims are drawn to specific doses of bupropion SR and venlafaxine. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely depressed patient or one having an unusually refractory depression would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to use the doses recited. Such a modification would have been motivated by the reasoned expectation of producing an anti-depressant/narcotic antagonist composition which is effective in comprehensively treating persons suffering from refractory depression characterized by dissociative symptoms.

Regarding the step of evaluating the patient by a conventional method such as use of the Glover Numbing Scale is obvious since the psychiatrist must evaluate the

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patient to determine if a particular drug is effective in treating a mental condition such as depression characterized by dissociative symptoms.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

